

IMMUNOBIOLOGICS

IMMUNOBIOLOGIC	PRIMARY IMMUNIZATION SCHEDULE	BOOSTER SCHEDULE	COMMENTS AND CONTRAINDICATIONS
<p>Smallpox (Vaccinia) Vaccine, Live</p> <p>ACAM2000® Acambis, Inc.</p>	<p>All ages if indicated*:</p> <p>First: 15 punctures with bifurcated needle into the upper arm over the insertion of the deltoid muscle**</p> <p>All vaccine providers must receive education on the proper administration as required by the U.S. Food and Drug Administration. All vaccine providers also receive a Medication Guide to distribute to each vaccinee prior to administering the vaccine. In the event of an actual smallpox emergency, declared by the Secretary of the U.S. Department of Health and Human Services, vaccine providers may follow educational instructions they receive from the manufacturer, such as how to educate vaccinees without a Medication Guide.</p> <p>Contact the Los Angeles County Immunization Program regarding resources for training on vaccination techniques and guidelines.</p> <p>The schedule for smallpox vaccine is one successful dose (i.e., a dose that results in a major reaction at the vaccination site). A vesicular or pustular skin lesion at the site of inoculation 6-8 days postvaccination indicates a successful vaccination, or 1 take.†</p> <p>Individuals who are not successfully vaccinated (i.e., vaccination failures) after primary vaccination may be revaccinated again in an attempt to achieve a satisfactory take. The vaccination procedures should be checked, and vaccination repeated with vaccine from another vial or vaccine lot.</p> <p>If a repeat vaccination is conducted using vaccine from another vial or vaccine lot fails to produce a major reaction, healthcare providers should consult the Centers for Disease Control and Prevention (CDC) at (404) 639-3670 or contact the Los Angeles County Immunization Program at (213) 351-7800.</p> <p>*Before the eradication of smallpox, vaccinia vaccination was administered routinely during childhood. However, smallpox vaccination is no longer indicated for infants or children for routine nonemergency indications. In an</p>	<p>Persons at continued high risk of exposure to smallpox (e.g., research laboratory workers handling variola virus) should receive repeat vaccination every three years</p> <p>Dose: 15 punctures with bifurcated needle into the skin over the deltoid muscle</p> <p>Successful vaccination in an individual previously exposed to vaccine is confirmed when a major cutaneous reaction is observed 6 to 8 days post-vaccination. However any prior vaccination may modify (reduce) the cutaneous response upon revaccination such that the absence of a cutaneous response does not necessarily indicate vaccination failure. Previously vaccinated individuals who do not have a cutaneous response on revaccination do not require revaccination to try to elicit a cutaneous response.</p>	<p>For routine nonemergency use (i.e., in the absence of smallpox disease) vaccination is recommended for laboratory workers who directly handle cultures or animals contaminated or infected with nonhighly attenuated vaccinia viruses, and recombinant vaccinia viruses derived from nonhighly attenuated vaccinia strains, for laboratory workers exposed to other orthopoxviruses that infect humans (e.g., monkeypox or cowpox), and consider vaccination for healthcare workers who come into contact with materials such as dressings that may be contaminated with vaccinia or recombinant vaccinia. Vaccination is also recommended for public health, hospital, and other personnel who may need to respond to a smallpox case or outbreak, and for persons who administer the vaccine to others. In the event of an intentional release of variola virus, vaccination would be recommended for those exposed to the initial release, contacts of persons with smallpox, and others at risk of exposure.</p> <p>Care of Vaccination Site: It is important that the vaccination site be covered to prevent dissemination of virus. Cover vaccination site with gauze loosely secured by first aid adhesive tape (taking care to obtain history of tape sensitivity). When working in a health care setting, vaccinees should keep their vaccination site covered with gauze or a similar absorbent material. This dressing should, in turn, be covered with a semipermeable dressing. Products combining an absorbent base with an overlying semipermeable layer also can be used to cover the vaccination site. Healthcare workers do not need to be placed on leave after receiving a smallpox vaccination.</p> <p>Vaccinees in settings where close personal contact is likely (such as parents of infants and young children) should cover the vaccination site with gauze or a similar absorbent material, wear a shirt or other clothing that would cover the vaccination site, and also make sure to practice good hand hygiene.</p> <p>Note: The use of semipermeable dressing alone could cause maceration of the vaccination site and increased, prolonged irritation and itching at the site, thereby increasing touching, scratching, and contamination of the hands. Thus, only persons working in healthcare settings should use semipermeable dressings (over gauze or a similar absorbent material as described above).</p> <p>Adverse Reactions: soreness at the vaccination site, swelling and tenderness of regional lymph nodes, local satellite lesions, local edema; headaches, fever, malaise, myalgia, and intense erythema ringing the vaccination site, erythematous or urticarial rashes. Suspected cases of myocarditis and/or pericarditis have been observed in healthy adult primary vaccinees. Encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalized vaccinia, severe vaccinia skin infections, and erythema multiforme major (including STEVENS-JOHNSON SYNDROME) and eczema vaccinatum resulting in permanent sequelae or death, ocular complications, blindness, and fetal death have occurred following either primary vaccination or revaccination with smallpox vaccines. Live vaccinia virus can be transmitted to persons who have close contact with the vaccinee and the risks in contacts are the same as those for the vaccinee.</p> <p>Contraindications & Precautions during nonemergency vaccine use:</p> <ul style="list-style-type: none"> History of anaphylactic reaction to a prior dose of vaccine or to any vaccine component Immunosuppression (or immunosuppressed household contact) from leukemia, lymphoma, or generalized malignancy; solid organ or stem cell transplantation; and cellular or humoral immunity disorders, including HIV infection. Persons on immunosuppressive therapies, including alkylating agents, antimetabolites, radiation, or high-dose corticosteroid therapy (i.e., prednisone doses of 2 milligrams per kilogram of body weight per day or higher, or 20 milligrams per day or higher for 14 days) Eye disease treated with topical steroids

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	<p>routine nonemergency indications. In an emergency (postrelease) situation, there would be no age limit for vaccination of persons exposed to a person with confirmed smallpox.</p> <p>**No skin preparation should be performed unless the skin at the intended site of vaccination is obviously dirty, in which case an alcohol swab(s) may be used to clean the area. If alcohol is used, the skin must be allowed to dry thoroughly to prevent inactivation of the live vaccine virus by the alcohol.</p>	<ul style="list-style-type: none"> • History of a heart condition or anyone with 3 or more of the following 5 risk factors: high blood pressure, high blood cholesterol, diabetes, have a first degree relative who had a heart condition before the age of 50, smoke cigarettes now • Pregnancy or to household contacts of pregnant women • Breastfeeding mothers • Infants < 12 months of age • Eczema or past history of eczema or for those whose household contacts have eczema • Persons with acute, chronic, or exfoliative skin conditions, (e.g., atopic dermatitis, wounds, burns, impetigo, or varicella zoster) and household contacts of such individuals until the condition is controlled or resolves. • Moderately or severely ill, defer vaccination until recovered <p>There are very few absolute contraindications for persons at high risk for smallpox. Individuals with severe immunodeficiency who are not expected to benefit from the vaccine should not receive ACAM2000. These individuals may include individuals who are undergoing bone marrow transplantation or individuals with primary or acquired immunodeficiency who require isolation.</p>
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